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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,789	10/08/2008	John Geoffrey Pickering	2817 P 002	6085

7590 09/27/2011

McDERMOTT WILL & EMERY
227 West Monroe Street
Chicago, IL 60606-5096

EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
09/27/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/577,789	PICKERING ET AL.
	Examiner	Art Unit
	KELAGINAMANE T. HIRIYANNA	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2011*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-46 are presently pending and subject to the following restrictions/elections:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims (1-3) 4, 20-22 and 28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by increasing its intracellular concentration wherein said increasing is carried out by administering PEBF protein or polypeptide, classified in class 424, subclass 93.1.

II. Claims (1-3), 4 5-6, 20-22 and 28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by increasing its intracellular concentration wherein said increasing is carried out by administering PEBF by gene therapy, classified in class 514, subclass 44.

Note: Claim 7 is currently improperly dependent from **claim 3** as it does not involve administration of PBEF. Applicant should change it to depend from claim 2. However, for the restriction purposes claim 7 is assigned **claim 2** as the parent claim.

III. Claims (1-2, 7), 8-9, 20-22 and 28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by increasing its intracellular concentration wherein said increasing is carried out promoting the endogenous production of PEBF that is effected by up-regulating the nucleic acid processes that increase PBEF production, classified in class 514, subclass 44.

IV. Claims (1-2, 7), 10, 20-22 and 28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by increasing its intracellular concentration wherein said increasing is carried out promoting the endogenous production of PEBF that is effected by down-regulating the nucleic acid processes that repress PBEF production, classified in class 514, subclass 44.

V. Claims (1, 11, 14), 12-13, 20-22 and 28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by administering a modulator of PEBF wherein said modulator is PRPP, classified in class 514, subclass 44.

VI. Claims (1, 11, 14-15) 13 and 16 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by promoting the endogenous production of PRPP effected by up-regulating the nucleic acid processes which increase the production of PRPP, classified in class 514, subclass 44..

VII. Claims (1, 11, 14-15), 13, 17 20-22 and 28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by promoting the endogenous production of PRPP effected by down-regulating the nucleic acid processes which repress the production of PRPP, classified in class 514, subclass 44..

VIII. Claims (1, 11, 14), 13, 18-22 and 28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by increasing the concentration of a modulator wherein the modulator is PRPP given in combination with at least one form of nicotinamide, classified in class 514, subclass 44..

IX. Claims (1) 20-22, 23-28 drawn to a method of treating diseases by optimizing intracellular concentration of PBEF by increasing the intracellular concentration of at least one precursor of PBEF, classified in class 514, subclass 44..

X. Claim 29-37 drawn to a composition for optimizing the intracellular concentration of NAD, said composition comprising an effective amount of PBEF, classified in class 424.

XI. Claim 38-46 drawn to a composition for optimizing the intracellular concentration of NAD, said composition comprising an effective amount of PRPP, classified in class 424.

Claim 1 link(s) inventions I-IX, Claim 2 link(s) inventions I-IV, Claim 3 links inventions I-II, Claim 7 links inventions III & IV, claim 11 & 14 link inventions V-VIII, and claim 15 links inventions VI-VII. The restriction requirement between the linked inventions is **subject to** the non-allowance of the linking claim(s). Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-IX are directed to related processes. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, each of the inventions I-IX as claimed involve therapy using compounds or combination of compounds which have distinct structure and therapeutic properties and therapy with said distinct therapeutic compounds can have different mode of operations, functions or effects. For example inventions in group I involve administering protein for therapy and inventions in group II involve administering nucleic acids that encode said protein and they are distinct in their therapeutic designs and mode of operation. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I-IX and inventions X-XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product namely the composition of various compounds in Inventions X can be used for in vitro enzyme assays.

Inventions X and XI are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can

have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the product/composition invention as claimed in Group X differs from that of Group XI by having a structurally compound in base composition. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The examiner has required restriction between sub-combinations usable together. Where applicant elects a sub-combination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all

the limitations of the allowable sub-combination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement

will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the grounds that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Species Elections

This application contains claims directed to the following patentably distinct species:

Should Applicant elect Group I from above, the.

(a). Applicant is required to choose a single species of PBEF administration route among the routes recited as a Markush group in claim 4.

(b). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group II from above, the

(a). Applicant is required to choose a single species of PBEF administration route among the routes recited as a Markush group in claim 4.

(b). Applicant is required to chose a single species of a viral vector among the viral vectors recited as a Markush group in claim 6.

(c). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group III from above, the.

(a). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group IV from above, the.

(a). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group V from above, the

(a). Applicant is required to choose a single species of modulator administration route among the routes recited as a Markush group in claim 13.

(b). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group VI from above, the

(a). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group VII from above, the.

(a). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group VIII from above, the.

(a). Applicant is required to choose a single species of nicotinamide compound or substitutes among the nicotinamide compounds and substitutes recited as a Markush group in claims 19.

(b). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

Should Applicant elects Group IX from above, the.

(a). Applicant is required to choose a single species of disease or condition treated among the diseases, conditions or their sub-genera recited as a Markush group in claims 20-22 combined.

(b). Applicant is required to choose a single species of precursor adminsitraion route among the administration routes recited as a Markush group in claims 25.

(c). Applicant is required to choose a single species of nicotinamide compound or substitutes among the nicotinamide compounds and substitutes recited as a Markush group in claims 27.

Should Applicant elects Group X from above, the

(a). Applicant is required to choose a single species of nicotinamide compound or substitutes among the nicotinamide compounds and substitutes recited as a Markush group in claim 33

(b) Applicant is required to choose a single species of pharmaceutically effective components among the components recited as a Markush group in claim 34.

(c) Applicant is required to choose a single species of administration route among the routes recited as a Markush group in claim 35.

(d) Applicant is required to choose a single species of form of the composition used in administration from among the forms recited as a Markush group in claim 36.

(e) Applicant is required to choose a single species of cosmetics, buffers, carriers etc among the recited as a Markush group in claim 37.

Should Applicant elects Group XI from above, the

(a) Applicant is required to choose a single species of nicotinamide compound or substitutes among the nicotinamide compounds and substitutes recited as a Markush group in claim 42.

(b) Applicant is required to choose a single species of pharmaceutically effective components among the components recited as a Markush group in claim 43.

(c) Applicant is required to choose a single species of administration route among the routes recited as a Markush group in claim 44.

(d) Applicant is required to choose a single species of form of the composition used in administration from among the forms recited as a Markush group in claim 45.

(e) Applicant is required to choose a single species of cosmetics, buffers, carriers etc., among the recited as a Markush group in claim 46.

The species so restricted above are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic to at least one group of species.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing**

the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is (571) 272-3307. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.,* may be reached at (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of

document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/
Primary Examiner, Art Unit 1633